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Patent
Attorney's Docket No. 029395-017

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE **RECEIVED**

In re Patent Application of)
Joyce TAYLOR-PAPADIMITRIOU et al.) Group Art Unit: 1644 TECH CENTER 1600/2900
Application No.: 09/658,621) Examiner: Amy M. Decloux
Filed: September 8, 2000) Confirmation No. 3359
For: MUC-1 DERIVED PEPTIDES)

RESPONSE TO SECOND RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In complete reply to the Office Action dated February 11, 2003 (Paper No. 19) setting forth a second restriction requirement in the subject application, Applicants hereby make the following **election with traverse**.

In Paper No. 19, the restriction requirement set forth in Paper No. 10 is set aside and a new restriction requirement is set forth. Group I, formerly elected by Applicants, is now canceled and rejoined with Groups 2-34. Groups 35, 71, and 140 have been canceled.

The present restriction requirement is respectfully traversed, because it is not in conformance with either U.S. Patent and Trademark Office policy as set forth in the M.P.E.P. or relevant law. Moreover, Applicants respectfully submit that the present restriction requirement is against sound public policy. The requirement is wasteful of Office resources, Applicants resources, and public resources and should be reconsidered.

Applicants request rejoining of Groups 2-34 and examination of the entirety of Claims 1-3, 17, 18, 20-22 and 37 on the merits. Alternatively, Applicants request that the present election be treated as a provisional election for examination purposes. In addition, Applicants request rejoining of Groups 36-70 with the corresponding Groups 2-34. In view of the substantial overlap in subject matter, examining these groups together would not be a serious burden.

The restriction requirement is not in conformance with the law.

Claim 1 is generic to at least the species recited in Claims 2 and 3 of the present application. However, the scope of Claim 1 is not limited to the species recited in Claims 2-3. By contrast, the present restriction requirement does not provide for examination of any species encompassed by generic Claim 1, or its dependant claims, that is not recited in Claims 2-3. Thus, the present restriction requirement does not allow for examination of the full scope of Claim 1. This is clearly unjust and is not consistent with relevant case law.

The Court of Customs and Patent Appeals (C.C.P.A.), in *Weber*, held that an applicant is entitled to claim his invention with the limitations he regards as necessary to circumscribe that invention within the requirements of 35 U.S.C. § 112. *In re Weber*, 198 U.S.P.Q. 328, 331 (C.C.P.A. 1978) ("[A]n applicant has a right to have *each* claim examined on the merits.") (emphasis in original).

This restriction requirement violates the principal of justice underlying the findings of the court in *Weber*. In their decision, the court expressed concern that the applicants would be denied the right to ever claim the entire invention if a claim reciting a Markush group were divided across multiple applications. *In re Weber* at 331-2. If the present Restriction Requirement is not withdrawn, Applicants would never be able to have their invention fully examined on the merits as they have disclosed it. Such a result is clearly contrary to the reasoning of the court in *Weber* and, therefore, is improper. *In re Weber* at 331-2.

Therefore, Applicants request rejoining of Groups 2-34 and examination of Claim 1 in its entirety. Applicants alternatively request, at a minimum that the election given herein be treated as a provisional election of a species for examination purposes. M.P.E.P. § 809.02. If the elected species is found allowable, then the search should be expanded to examine the generic claims in their entirety.

The restriction requirement is not in conformance with the M.P.E.P.

The restriction requirement is not in conformance with M.P.E.P. § 803.02.

The M.P.E.P. sets forth guidelines for restriction practice in the case of Markush-type claims. This application contains Markush-type claims, for example, Claims 2 and 3 of Groups 2-34. However, this restriction requirement does not conform with the guidelines of M.P.E.P. § 803.02.

As set forth in MPEP § 803.02, first paragraph, the Examiner must examine all the members of a Markush group in a claim on the merits, even though they are directed to distinct and independent inventions, when the members are either sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden.

The Markush-groups of claims 2-3 depend from generic Claim 1 and recite sequences derived from SEQ ID NO: 1 of Claim 1. The members of the Markush groups are closely related so that a properly defined automated sequence search of SEQ ID NO: 1 should substantially overlap with a sequence search for any member of the Markush groups. Therefore, there would be no serious burden on the Examiner to examine the entire Markush groups. The claims should be examined in their entirety.

The second paragraph of MPEP § 803.02 cites the decisions of *In re Weber* and *In re Harnisch* in acknowledging that it is improper for the U.S. Patent and Trademark Office to refuse to examine that which applicants regard as their invention unless the subject matter lacks unity of invention. *In re Weber*, 198 U.S.P.Q. 328 (C.C.P.A. 1978); *In re Harnisch*, 206 U.S.P.Q. 300 (C.C.P.A. 1980).

In *Harnisch*, the C.C.P.A. extended the findings of *Weber* to hold that a determination of propriety of a Markush type claim is based on a unity of invention standard. *In re Harnisch* at 305. Unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. *See*, MPEP § 803.02, second paragraph.

Alternatively stated, a Markush grouping is proper when the substances have "a community

of chemical or physical characteristics" which justify their inclusion in a common group and that such inclusion is not repugnant to principles of scientific classification. *See, e.g., In re Harnisch* at 305; *In re Jones*, 74 U.S.P.Q. 149, 151 (C.C.P.A. 1947). In the present case, the grouped members are structurally related in that they are sequences of no more than 20 consecutive amino-acids of SEQ ID NO: 1, and bind at least one MHC-I glycoprotein. The grouped members also share at least one common utility and are taught as capable of being used together. See for example, pages 13-14 of the specification describing vectors capable of expressing more than one polypeptide of the Markush groups and compositions comprising a plurality of such polypeptides. Therefore, there is unity of invention in the Markush groups of the instant application in accordance with Markush claim practice.

Moreover, MPEP § 803.02 goes on to state as follows:

A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to

determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

. . .

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final.

Applicants respectfully request that the restriction requirement between the species recited in the Markush groups of the present claims be reconsidered and that the claims be examined in conformance with M.P.E.P. § 803.02. Thus, the entire claims should be

examined on the merits, or, at the very least, the present election should be treated as a provisional election for examination purposes in accordance with the above.

The restriction requirement is not in conformance with M.P.E.P. § 803.04. The high number of groups in the present restriction requirement appears to be largely due to the fact that the claims recite biomolecular sequences. Groups 2-34, 36-70, 72-104, and 105-139 are divided between claims encompassing nucleic acid and polypeptide sequences. Each group being restricted to claims encompassing a single sequence. This is clearly not in conformance with M.P.E.P. § 803.04, wherein it is stated that "It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." The policy reason for this has been given. "[T]o further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996)."

Applicants note that this policy has been affirmed in the latest edition of the M.P.E.P., 8th Edition, Latest Revision February 2003. At the very least, at least 10 sequences should be examined. If claims encompassing those sequences are found

allowable, additional sequences should be examined to extend examination to the generic claim and the entire Markush groups.

The restriction requirement is not in conformance with M.P.E.P. § 808.02.

The polypeptides of Groups 2-34 and the analogs of Groups 36-70 are related at least in that they are disclosed as being capable of being used together. M.P.E.P. § 806.05. See page 14 of the specification. Likewise the polynucleotides of Groups 72-104 and 105-139 are also related. M.P.E.P. § 808.02 sets forth the requirements for showing reasons for insisting upon restriction. However, the required showing is not made in either Paper No. 10 or Paper No. 19. Groups 2-34 and 36-70 are shown as classed in the same classes and subclasses. There is no showing that the subject matter of the groups has attained a separate status in the art. The subject matter of these groups is certainly in the same field of search. The M.P.E.P. states: "Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions." M.P.E.P. § 808.02.

The restriction requirement is contrary to sound public policy

The guidelines of the M.P.E.P. demonstrate that restriction practice is intended to maintain a balance which respects the interests of the Office, Applicants, and the public. The M.P.E.P. evidences a policy of reasonableness and does not call for a hypertechnical

application of restriction rules. By contrast, this requirement for restriction is wasteful of Office resources, Applicants resources, and public resources.

The requirement will be wasteful of Office resources. If the present requirement for restriction is not reconsidered, Applicants could be required to seek examination of this application for each of the 135 remaining groups, filing 136 separate copies of this application, resulting in 136 closely related patents. The amount of redundant formalities examination, clerical work and examination on the merits and the associated Office overhead consumed by such an undertaking will be a staggering waste when considered against the minimal burden of examining the entire application in one or two cases as is appropriate considering the relatedness and overlapping subject matter of the inventions disclosed in this application.

The public will suffer a burden if this restriction requirement is not reconsidered. If Applicants are forced to prosecute and obtain 136, or more, patents drawn to the related aspects of the invention disclosed in this application, public resources will be wasted for anyone interested in working in the field of the invention. The public member wishing to know what is covered and what is not covered will be forced to study each of the very many divisional patents, and its file, to determine the bounds of patented invention which will shift as each subsequent divisional patent is issued. This will impose a staggering burden on anyone interested in making or using this invention or practicing in a related field.

If the present restriction requirement is allowed, the cost to Applicants to protect the entire invention disclosed in the present application will be unnecessarily excessive. The

aspects of the invention disclosed in this application are not unrelated. In view of the interrelated nature of the aspects of the invention it is perfectly reasonable, and allowed under the relevant statutes, rules and guidelines of the M.P.E.P. to seek protection for those aspects together. To impose such an excessive burden on Applicants is contrary to the Constitutional purpose of advancing the useful arts. Furthermore, the issuance of a second requirement revoking Applicants first election and requiring a second response is wasteful of both Office resources and Applicants' resources both in considering and preparing a response and in eventual loss patent term caused by drawing out the examination of the application.

For at least these reasons, the restriction requirement does not reflect sound public policy as sought for in the M.P.E.P. and should be reconsidered.

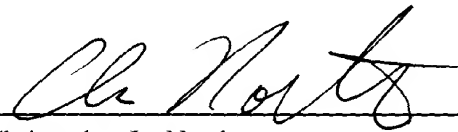
Election

Pursuant to 37 C.F.R. § 1.143, Applicants hereby indicate an election of Group 25 comprising Claims 1-3, 17, 18, 20-22 and 37 encompassing SEQ ID NO: 26, subject to the above traversal.

In the event that there are any questions relating to this Reply to Restriction Requirement, or the application in general, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Date: April 11, 2003